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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,626	07/25/2002	Cynthia Green	2159.0960004/EKS/PAC	3311
53644	7590	10/24/2006	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX, P.L.L.C. 1100 NEW YORK AVE., N.W. WASHINGTON, DC 20005			OUSPENSKI, ILIA I	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,626

Applicant(s)

GREEN ET AL.

Examiner

ILIA OUSPENSKI

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/21/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's Petition under 37 CFR 1.137(b) for revival of this application, filed on 03/07/2006, has been approved by the Office of Petitions on 09/12/2006.

2. Applicant's amendment/remarks, filed 03/07/2006, are acknowledged.

Claims 1 – 16 and 18 – 25 have been cancelled.

Claims 17 and 26 have been amended.

Claims 17 and 26 are pending.

3. It is noted that certain distinct and independent inventions, which are encompassed within the scope of the instant claims, have been withdrawn from consideration by the Examiner as being drawn to nonelected inventions (see Office Action mailed 08/15/2005).

Claims 17 and 26 are under consideration in the instant application, as they read on a method of treating or preventing a disorder by administering a an antibody to polypeptide of SEQ ID NO:6.

Applicant is reminded that the pending claims read on non-elected embodiments of the invention, which are not under consideration in the instant application (see Restriction Requirement mailed 03/07/2005). In order to facilitate prosecution, Applicant is requested to cancel the non-elected embodiments.

4. This Office Action will be in response to applicant's amendment and arguments, filed 03/07/2006.

The rejections of record can be found in the previous Office Action, mailed 08/15/2005.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

5. The objections and rejections of record have been withdrawn in view of Applicant's amendment and arguments, except as set forth herein.

6. Applicant's IDS, filed 03/21/2006, is acknowledged, and has been considered.

7. Applicant's claim for domestic priority under 35 U.S.C. 119(e) and 35 U.S.C. 120:

The claims have been accorded the priority of the filing date of the priority PCT application, i.e. 08/31/2000, because the provisional applications USSN 60/152,383, 60/172,909, and 60/183,578 have not been found to provide sufficient support under 35 U.S.C. 112 the limitations of "a method of treating or preventing an immune disorder by administering an effective amount of an antibody to a polypeptide of SEQ ID NO:6."

Applicant argues points to passages in the provisional application USSN 60/183,578 at Figure 1 and page 3 that disclose the polypeptide sequence of SEQ ID NO:6, that proteins of the invention are important in the modulation of immune responses and useful in potential therapeutic applications, and that nucleic acids and

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proteins of the invention are useful in the generation of antibodies for use in therapeutic methods.

This is not found persuasive, because the reference to therapeutic usefulness of an antibody is not seen as supporting the recitation of "treating and preventing" any disorder, or specifically "immune disorder." Further, no adequate support has been identified for the recitation of "administering an effective amount" of the recited antibody.

Therefore, the instant claims are considered to have the priority of the filing date of the priority PCT application, i.e. 08/31/2000.

8. Claims 17 and 26 stand rejected under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not provide a sufficient enabling description of the claimed methods of treating or preventing and immune response associated disorder, or a pathological state.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that there are examples where sequence homology is an accurate predictor of protein function.

This is not found persuasive, because regarding the instantly recited SEQ ID NO:6 in particular, it was well known in the art at the time the invention was made that different molecules having sequence similarity to costimulatory molecules B7-1 and B7-

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2, like SEQ ID NO:6, may have different, and often opposite, functions (e.g. reviewed by Riley et al., 2005, Blood, 105: 13 – 21; see entire document), as discussed in the previous Office Action.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection or record is incorporated by reference herein, as if reiterated in full.

9. Claims 17 and 26 are rejected under **35 U.S.C. 102(e)** as being anticipated by Mikesell et al. (US Pat. Pub. No. 2002/0095024; see entire document).

Applicant argues that priority of provisional application USSN 60/183,578 should be accorded to the instant claims, and therefore the reference of Mikesell et al. would not anticipatory.

Applicant's argument has been addressed in section 6 supra, and has not been found convincing.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection or record is incorporated by reference herein, as if reiterated in full.

10. Conclusion: no claim is allowed.

11. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI
Patent Examiner
Art Unit 1644


PHILLIP GAMBEL, PH.D. *JD.*
PRIMARY EXAMINER

R 1600

10/5/06

October 3, 2006